DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Simpleware LTD.
% Dr. Gareth James
Marketing and PR Officer
Bradninch Hall Castle Street
EXETER, GB EX43PL DEVON

Re: K142779
Trade/Device Name: ScanIP; ScanIP: Medical Edition; ScanIP: Med
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: March 19, 2015
Received: March 25, 2015

Dear Dr. James:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

Robert Ochs, Ph.D.
Acting Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142779

Device Name
ScanIP ; ScanIP: Medical Edition; ScanIP: Med

Indications for Use *(Describe)*
ScanIP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options. ScanIP is not intended to be used for mammography imaging.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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2.2 Updated 510(k) Summary

(as required by 21 CFR 807.92c)

I. SUBMITTER

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Date Prepared: March 16th 2015

II. DEVICE

Name of Device: ScanIP; ScanIP: Medical Edition; ScanIP: Med

Common or Usual Name: Image processing system and preoperative software for simulating and evaluating surgical treatment options

Classification Name: Picture Archiving and Communications System (21 CFR 892.2050)

Regulatory Class: II

Product Code: LLZ

III. PREDICATE DEVICE

Manufacturer	Device	510(k) Number
Materialise N.V.	Mimics	K073468

No reference devices were used in this submission.

IV. Device Description

ScanIP represents a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. ScanIP provides a core image processing interface with several additional modules available to users – these include +CAD, +FE and +NURBS – which provide further options for working with image data. +CAD enables the integration of computer-aided design (CAD) drawings such as implants with patient-specific data; +FE allows segmented image data to be exported as computational models for physics-based simulations in other software; +NURBS is designed to allow users to export segmented data as NURBS IGES files to CAD software.

ScanIP is written in C++ and designed using the integrated development environment (IDE) Microsoft Visual Studio. Minimum hardware requirements for the operating system are Windows 7, Windows 8, Windows Vista, and Windows XP. 32 and 64 bit versions of the software are available. Minimum processor requirements are an Intel Core i3 or equivalent; minimum memory requirements for the software to run are 4096 MB (4GB), while an OpenGL compatible graphics card with 32 MB of RAM is required. The screen resolution of a workstation should be a minimum of 1024 x 768 high colour (16 bit), and 10 GB of disk space is recommended as a minimum.

The software is required to be able to visualise and process medical images using a range of filters and tools, and can export models as output files. ScanIP meets DICOM standards for the transfer of medical images. The software is also intended for use in the early stages of pre-surgical planning for visualising patient-specific data, taking measurements and obtaining statistics (such as bone density, distances and angles between arteries), and for integrating computer drawings of implants with patient data to evaluate fitness for use. This functionality has applications to implant evaluation and export of models for simulation in other software. Output files can be used in these other applications; ScanIP does not integrate with them directly.

Processed medical images can also be exported as output files to 3D printing processes for the creation of physical models that can be used in pre-surgical planning (inspection of implant fit), and as computational models to other software programs for running simulations (e.g. stress/strain limits in bone, fluid flow through vessels and airways).

ScanIP has FDA clearance to generate 3D models and export these models in a format suitable for 3D printing to be used as physical models for visualization or educational purposes only. This clearance does not cover medical devices manufactured from those output files.

The intended environment for use is by a trained professional working on a standard workstation (see recommended hardware specifications above). The clinician receiving images and models from the software retains the ultimate responsibility for making a

decision based on their surgical applications and patient assessment, using their standard practices and visual comparison of the information with original scans.

ScanIP and its related modules has been commercially available since 2004, but has previously not required FDA clearance as it was marketed for research use only, rather than for potential clinical applications.

V. INDICATIONS FOR USE

ScanIP is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner or a Magnetic Resonance Imaging scanner to an output file. It is also intended as pre-operative software for simulating/evaluating surgical treatment options. ScanIP is not intended to be used for mammography imaging.

The Indications for Use statement for ScanIP is identical to that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ScanIP is considered to be substantially equivalent to Mimics (K073468) from Materialise (Establishment Registration No: 3003998208). The two devices provide software capabilities for importing and processing medical images, and for exporting output files. Both devices are voluntarily compliant with the ACR/NEMA Digital Imaging and Communication in Medicine (DICOM) Standard (Version 3.0).

At a high level, the subject and predicate devices are based on the following equivalent technological elements:

- The visualisation, segmentation, processing and file export of medical images through the application of software algorithms, filters and tools
- Compatibility with scanner data (e.g. MRI, CT, micro-CT…)
- The ability to visualise data in 2D and 3D views
- Use of tools to take measurements and record statistics
- Use of algorithms to create surface meshes (e.g. STL)
- Use of filters for morphological image processing
- Use of tools for 3D editing (e.g. paint)
- Use of tools for segmenting images (e,g. thresholding)
- Export files can be used in Finite Element Analysis (FEA) software
- Export files can be used in CAD software
- Export files can be used in 3D printing processes (please see 3D printing statement for limitations on this use)

The following technological differences exist between the subject and predicate devices:

- Predicate device has dedicated surgical planning modules and subject device does not

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for the Industry and FDA Staff: 'Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.' Testing include system level tests and validation testing.

The software for this device was considered as a "Moderate" level of concern, as, prior to mitigation of hazards, a failure of the device could result in minor injury. A failure or misuse of ScanIP, such as misinterpreting scanned data, could in exceptional circumstances cause a minor injury to a patient. This could take the form of a surgical implant design being incorrectly positioned, for example. Software documentation, including verification and validation activities and related performance data, has been provided to demonstrate that appropriate steps have been taken to ensure mitigation of potential risks.

VIII. CONCLUSIONS

Verification and validation testing of ScanIP, and inclusion of the subject device's Reference Guide and the predicate's Reference Guide supports substantial equivalence based on performance testing and detailed descriptive criteria. It is therefore believed that ScanIP is substantially equivalent with respect to safety and effectiveness as the predicate device that is currently marketed for the same intended use.